

THERAPLEX HEALING EMOLLIENT- petrolatum cream

The Theraplex Company, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Theraplex Healing Emollient

Drug Facts

Active Ingredient

Petrolatum (65%)

Purpose

Skin Protectant

Uses

• temporarily protects and helps relieve chapped or cracked skin and lips • helps protect from the drying effects of wind and cold weather • temporarily protects minor: • cuts • scrapes • burns

Warnings For external use only

When using this product do not get into eyes.

Stop and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days

Do not use on • deep or puncture wounds • animal bites • serious burns

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions apply as needed, or as directed by your doctor.

Other information • store at room temperature • keep from freezing

Inactive Ingredients cyclomethicone, microcrystalline wax

Questions? call **1-888-437-2753**

Clinically-proven **Theraplex Healing Emollient** combines a unique enriched special petrolatum fraction (ESPF) with a novel hydrosilicone delivery system that deeply penetrates severely dry skin. Dermatologists have recommended this healing formulation for years because of its ability to deliver soothing moisturization and long-lasting skin barrier protection with no irritation to sensitive, compromised skin.

- **Noncomedogenic (Won't Clog Pores)**
- **Hypoallergenic**
- **Preservative-Free**
- **Fragrance-Free**
- **Paraben-Free**
- **Gluten-Free**

Skin Protectant • For Severely Dry & Sensitive Skin

Dermatologist recommended for adults & children

Distributed by:
The Theraplex Company, LLC
Memphis, TN 38119
www.theraplex.com

Packaging

Drug Facts Active Ingredient Petrolatum (65%) Purpose Skin Protectant Uses temporarily protects and helps relieve chapped or cracked skin and lips ■ helps protect from the drying effects of wind and cold weather ■ temporarily protects minor: ■ cuts ■ scrapes ■ burns Warnings For external use only When using this product do not get into eyes. Stop and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions apply as needed, or as directed by your doctor. Other information ■ store at room temperature ■ keep from freezing Inactive Ingredients cyclomethicone, microcrystalline wax Questions? call 1-888-437-2753	
<div> <div>theraplex®</div> <div>HEALING EMOLLIENT</div> <div>Skin Protectant • For Severely Dry & Sensitive Skin</div> <div>Dermatologist recommended for adults & children</div> <div>Net Wt. 8oz. (226.7g)</div> </div>	

Drug Facts Label

Drug Facts Active Ingredient Petrolatum (65%) Purpose Skin Protectant Uses temporarily protects and helps relieve chapped or cracked skin and lips ■ helps protect from the drying effects of wind and cold weather ■ temporarily protects minor: ■ cuts ■ scrapes ■ burns Warnings For external use only When using this product do not get into eyes. Stop and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions apply as needed, or as directed by your doctor. Other information ■ store at room temperature ■ keep from freezing Inactive Ingredients cyclomethicone, microcrystalline wax Questions? call 1-888-437-2753	
---	--



Bottom Label



Top Label

THERAPLEX HEALING EMOLLIENT

petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62917-065
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	65 g in 100 g

Inactive Ingredients				
Ingredient Name				Strength
CYCLOMETHICONE (UNII: NMQ347994Z)				
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62917-065-14	397 g in 1 JAR; Type 0: Not a Combination Product	05/01/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		05/01/2017	

Labeler - The Theraplex Company, LLC (363529392)